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Voluntary - Public

Date: 2010/05/28

GAIN Report Number: JA0018

Japan

Post: Tokyo

MRL changes in Azimsulfuron and other 7 chemicals

Report Categories:

Sanitary/Phytosanitary/Food Safety

Approved By:

Jeffrey Nawn

Prepared By:

Suguru Sato

Report Highlights:

On March 9, 2010, Government of Japan announced proposed changes to the MRLs for **Azimsulfuron** (herbicide), **Clofencet** (plant growth regulators), **Clomeprop** (herbicide), **Pyriproxyfen** (insecticide), **Pyrimisulfan** (herbicide), **Propamocarb** (fungicide), **Rafoxanide** (veterinary drug) and **Colistin** (feed additives and veterinary drugs). MHLW will notify these proposed changes to the WTO/SPS committee, which will provide a chance for public comments to be submitted on this subject.

General Information:

On March 9, 2010, Government of Japan announced proposed changes to the MRLs for **Azimsulfuron** (herbicide), **Clofencet** (plant growth regulators), **Clomeprop** (herbicide), **Pyriproxyfen** (insecticide), **Pyrimisulfan** (herbicide), **Propamocarb** (fungicide), **Rafoxanide** (veterinary drug) and **Colistin** (feed additives and veterinary drugs). The domestic public comment period has closed already. However, MHLW will notify these proposed changes to the WTO/SPS committee, which will provide a chance for public comments to be submitted on this subject.

The actual WTO-SPS notifications can be found at the site below.

http://www.wto.org/english/tratop_e/sps_e/work_and_doc_e.htm

After the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date; this will constitute the final decision.

In case you need to contact GOJ officials on this issue, the contact information is as below.

<Contact>

Standards and Evaluation Division,
Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
Tel: 03-5253-1111
Fax: 03-3501-4868

Pesticides

Mr. K. OGI (ogi-katsuhiko@mhlw.go.jp)
Ms. N. SARUTA (saruta-noriko@mhlw.go.jp)
Ms. A. NAKATA (nakata-ayumi@mhlw.go.jp)
Mr. H. WATANABE (watanabe-hidemi@mhlw.go.jp)
Ms. K. MIYOSHI (miyoshi-kanako@mhlw.go.jp)
Tel. ex. 2487

Veterinary drugs and Feed Additives

Mr. K. URAKAMI (uragami-kenji@mhlw.go.jp)

Mr. H. DEGUCHI (deguchi-haruyuki@mhlw.go.jp)

Mr. Y. ISHII (ishii-yasuhiroaa@mhlw.go.jp)

Tel. ex. 2489

Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov when you contact GOJ officials.

Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is responsible for developing the compositional specifications for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the MHLW is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just “agricultural chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed in Japan unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has newly established MRLs (draft) for some food commodities as well as has comprehensively reviewed the current MRLs. This activity is targeted to eight chemicals:

Azimsulfuron (herbicide), **Clofencet** (plant growth regulators), **Clomeprop** (herbicide), **Pyriproxyfen** (insecticide), **Pyrimisulfan** (herbicide), **Propamocarb** (fungicide), **Rafoxanide** (veterinary drug) and **Colistin** (feed additives and veterinary drugs). Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

Azimsulfuron (herbicide): This chemical is already permitted for use in Japan. The MHLW has reviewed the MRLs which had been provisionally established at the time of the introduction of the new system. For draft MRLs, see Attachment 1-1.

Clofencet (plant growth regulators): This chemical is not permitted for use in Japan. The MHLW has reviewed the MRLs which had been provisionally established at the time of the introduction of the new system. For draft MRLs, see Attachment 1-2.

Clomeprop (herbicide): This chemical is already permitted for use in Japan. The MHLW has reviewed the MRLs that had been provisionally established at the time of the introduction of the new system. Also, the MHLW has newly established a MRL (draft) for the “aquatic animals” category. For draft MRLs, see Attachment 1-3.

Pyriproxyfen (insecticide): This chemical is already permitted for use in Japan. This time Ministry of Agriculture, Forestry and Fisheries (MAFF) will expand the scope of target crops for which the use of the chemical is permitted. Also, an application has been filed by a foreign business with the MHLW for the establishment of MRLs for the chemical, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to the MAFF’s action and the manufacture’s application, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-4.

Pyrimisulfan (herbicide): This chemical is not permitted for use in Japan. This time MAFF has decided to approve the chemical based on the Agricultural Chemicals Regulation Law. In response to the MAFF’s action, the MHLW has newly established MRLs (draft) for some crops. For draft MRLs, see Attachment 1-5.

Propamocarb (fungicide): This chemical is already permitted for use in Japan. This time MAFF has decided to approve the chemical based on the Agricultural Chemicals Regulation Law. In response to the MAFF’s action, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-6.

The existing MRLs for **Azimsulfuron**, **Clomeprop**, **Clofencet** and **Propamocarb** appear in

Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. The MRLs currently placed in Item 7 will be deleted. And finalized MRLs for **Azimsulfuron**, **Clomeprop** and **Propamocarb** will be placed on the MRLs List in Item 6.

Rafoxanide (antiparasitics): This chemical is not permitted for use in Japan. The MHLW has comprehensively reviewed MRLs that had been provisionally established at the time of the introduction of the new system. For draft MRLs, see Attachment 1-7.

Colistin (antimicrobial): This chemical is permitted for use in Japan. The MHLW has comprehensively reviewed MRLs that had been provisionally established at the time of the introduction of the new system. For draft MRLs, see Attachment 1-8.

The existing MRLs for **Rafoxanide** and **Colistin** appear in Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. The MRLs currently placed in Item 7 will be deleted. And finalized MRLs for **Colistin** will be placed on the MRLs List in Item 6.

Azimsulfuron(herbicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.02	0.1
Wheat		0.02
Barley		0.02
Rye		0.02
Corn (maize, including pop corn and sweet corn)		0.02
Buckwheat		0.02
Other cereal grains ¹		0.02
Soybeans, dry		0.1
Beans, dry ²		0.02
Peas		0.02
Broad beans		0.02
Peanuts, dry		0.1
Other legumes/pulses ³		0.02
Potato		0.02
Taro		0.02

Sweet potato		0.02
Yam		0.02
Konjac		0.02
Other potatoes ⁴		0.02
Sugar beet		0.02
Japanese radish, roots (including radish)		0.02
Japanese radish, leaves (including radish)		0.02
Turnip, roots (including rutabaga)		0.02
Turnip, leaves (including rutabaga)		0.02
Horseradish		0.02
Watercress		0.02
Chinese cabbage		0.02
Cabbage		0.02
Brussels sprouts		0.02
Kale		0.02
<i>Komatsuna</i> (Japanese mustard spinach)		0.02
<i>Kyona</i>		0.02
Qing-geng-cai		0.02
Cauliflower		0.02
Broccoli		0.02
Other cruciferous vegetables ⁵		0.02
Burdock		0.02
Salsify		0.02
Artichoke		0.02
Chicory		0.02
Endive		0.02
<i>Shungiku</i>		0.02
Lettuce (including cos lettuce and leaf lettuce)		0.02
Other composite vegetables ⁶		0.02
Onion		0.02
Welsh (including leek)		0.02
Garlic		0.02
<i>Nira</i>		0.02
Asparagus		0.02
Multiplying onion (including shallot)		0.02
Other liliaceous vegetables ⁷		0.02
Carrot		0.02

Parsnip		0.02
Parsley		0.02
Celery		0.02
<i>Mitsuba</i>		0.02
Other umbelliferous vegetables ⁸		0.02
Tomato		0.02
Pimiento (sweet pepper)		0.02
Egg plant		0.02
Other solanaceous vegetables ⁹		0.02
Cucumber (including gherkin)		0.02
Pumpkin (including squash)		0.02
Oriental pickling melon (vegetable)		0.02
Water melon		0.02
Melons		0.02
<i>Makuwauri</i> melon		0.02
Other cucurbitaceous vegetables ¹⁰		0.02
Spinach		0.02
Bamboo shoots		0.02
Okra		0.02
Ginger		0.02
Peas, immature (with pods)		0.02
Kidney beans, immature (with pods)		0.02
Green soybeans		0.02
Button mushroom		0.02
<i>Shiitake</i> mushroom		0.02
Other mushrooms ¹¹		0.02
Other vegetables ¹²		0.02
<i>Unshu</i> orange, pulp		0.02
Citrus <i>natsudaidai</i> , whole		0.02
Lemon		0.02
Orange (including navel orange)		0.02
Grapefruit		0.02
Lime		0.02
Other citrus fruits ¹³		0.02
Apple		0.02
Japanese pear		0.02
Pear		0.02

Quince		0.02
Loquat		0.02
Peach		0.02
Nectarine		0.02
Apricot		0.02
Japanese plum (including prune)		0.02
Mume plum		0.02
Cherry		0.02
Strawberry		0.02
Raspberry		0.02
Blackberry		0.02
Blueberry		0.02
Cranberry		0.02
Huckleberry		0.02
Other berries ¹⁴		0.02
Grape		0.02
Japanese persimmon		0.02
Banana		0.02
Kiwifruit		0.02
Papaya		0.02
Avocado		0.02
Pineapple		0.02
Guava		0.02
Mango		0.02
Passion fruit		0.02
Date		0.02
Other fruits ¹⁵		0.02
Sunflower seeds		0.1
Sesame seeds		0.1
Safflower seeds		0.1
Cotton seeds		0.1
Rapeseeds		0.1
Other oil seeds ¹⁶		0.1
Ginkgo nut		0.02
Chestnut		0.02
Pecan		0.02
Almond		0.02

Walnut		0.02
Other nuts ¹⁷		0.02
Tea		0.1
Hop		0.1
Other spices ¹⁸		0.1
Other herbs ¹⁹		0.02

The uniform limit (0.01 ppm) is applied to commodities for which no numerical level is given in draft MRL.

The uniform limit is also applied to all other commodities not in this list.

Clofencet(plant growth regulators)

Commodity	MRL (draft) ppm	Current MRL ppm
Wheat		250
Cattle, muscle		0.2
Pig, muscle		0.2
Other terrestrial mammals ²⁰ , muscle		0.2
Cattle, fat		0.04
Pig, fat		0.04
Other terrestrial mammals, fat		0.04
Cattle, liver		0.5
Pig, liver		0.5
Other terrestrial mammals, liver		0.5
Cattle, kidney		10
Pig, kidney		10
Other terrestrial mammals, kidney		10
Cattle, edible offal ²¹		0.5
Pig, edible offal		0.5
Other terrestrial mammals, edible offal		0.5
Milk		0.02
Chicken, muscle		0.2
Other poultry animals ²² , muscle		0.2
Chicken, fat		0.04
Other poultry animals, fat		0.04
Chicken, liver		0.2

Other poultry animals, liver		0.2
Chicken, kidney		0.2
Other poultry animals, kidney		0.2
Chicken, edible offal		0.2
Other poultry animals, edible offal		0.2
Chicken, eggs		1
Other poultry, eggs		1

The uniform limit (0.01 ppm) is applied to all commodities.

Clomeprop(herbicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.02	0.1
Fish and shellfish	0.3	

The uniform limit (0.01 ppm) is applied to commodities not in this list.

MRLs for clomeprop are established for the sum of residues of clomeprop and its metabolites 2-(2,4-dichloro-m-tolyloxy) propionic acid, all calculated as clomeprop on aquatic products, and for the sum of the residue of clomeprop alone on other foods.

Pyriproxyfen(insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Soybeans, dry	0.2	0.2
Beans, dry ²	0.2	0.2
Peas	0.2	0.2
Broad beans	0.2	0.2
Other legumes/pulses ³	0.2	0.2
Chinese cabbage	0.7	0.7
Cabbage	0.7	0.7
Brussels sprouts	0.7	0.7
Kale	2.0	2.0
<i>Komatsuna</i> (Japanese mustard spinach)	2.0	2.0

<i>Kyona</i>	2.0	2.0
Qing-geng-cai	2.0	2.0
Cauliflower	0.7	0.7
Broccoli	0.7	0.7
Other cruciferous vegetables ⁵	2.0	2.0
Onion	0.15	0.15
Tomato	1	1
Pimiento (sweet pepper)	3	3
Egg plant	1	1
Other solanaceous vegetables ⁹	2	2
Cucumber (including gherkin)	0.2	0.2
Pumpkin (including squash)	0.1	0.1
Oriental pickling melon (vegetable)	0.1	0.1
Water melon	0.1	0.1
Melons	0.1	0.1
<i>Makuwauri</i> melon	0.1	0.1
Other cucurbitaceous vegetables ¹⁰	0.1	0.1
Okra	0.02	0.02
Peas, immature (with pods)	0.2	0.2
Kidney beans, immature (with pods)	0.2	0.2
Green soybeans	0.2	0.2
Other vegetables ¹²	0.2	0.2
<i>Unshu</i> orange, pulp	0.5	0.5
Citrus <i>natsudaidai</i> , whole	0.5	0.5
Lemon	0.5	0.5
Orange (including navel orange)	0.5	0.5
Grapefruit	0.5	0.5
Lime	0.5	0.5
Other citrus fruits ¹³	0.5	0.5
Apple	0.2	0.2
Japanese pear	0.2	0.2
Pear	0.2	0.2
Quince	0.2	0.2
Loquat	0.2	0.2
Peach	1.0	1.0
Nectarine	1.0	1.0
Apricot	1.0	1.0
Japanese plum (including prune)	1.0	1.0
Cherry	1.0	1.0

Strawberry	0.3	0.3
Blueberry	1.0	1.0
Cranberry	1.0	
Huckleberry	1.0	1.0
Other berries ¹⁴	1.0	1.0
Grape	0.5	0.5
Papaya	1.0	1.0
Avocado	1.0	1.0
Guava	0.1	0.1
Mango	1.0	1.0
Passion fruit	0.1	0.1
Other fruits ¹⁵	1.0	1.0
Cotton seeds	0.05	0.05
Chestnut	0.02	0.02
Pecan	0.02	0.02
Almond	0.02	0.02
Walnut	0.02	0.02
Other nuts ¹⁷	0.02	0.02
Tea	15	0.3
Other spices ¹⁸	1.0	1.0
Other herbs ¹⁹	2.0	2.0
Cattle, muscle	0.01	0.01
Other terrestrial mammals ²⁰ , muscle	0.01	0.01
Cattle, fat	0.01	0.01
Other terrestrial mammals, fat	0.01	0.01
Cattle, liver	0.01	0.01
Other terrestrial mammals, liver	0.01	0.01
Cattle, kidney	0.01	0.01
Other terrestrial mammals, kidney	0.01	0.01
Cattle, edible offal ²¹	0.01	0.01
Other terrestrial mammals, edible offal	0.01	0.01
Cottonseeds oil (limited to Ref.1)	0.01	0.01
Cottonseeds oil (except Ref.1)	0.01	0.01
Mineral waters (natural mineral waters and bottled/packageged drinking waters)	0.3	0.3

The uniform limit (0.01 ppm) is applied to commodities not in this list.

Ref.1 Refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter

than JAS.

Pyrimisulfan(herbicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.05	

The uniform limit (0.01 ppm) is applied to commodities not in this list.

Propamocarb(fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.1	0.1
Potato	0.3	0.5
Sugar beet	0.2	0.2
Japanese radish, roots (including radish)	1	5.0
Chinese cabbage	10	
Cabbage	0.1	0.1
Brussels sprouts	1.0	1.0
Qing-geng-cai	0.5	0.5
Cauliflower	0.2	0.2
Broccoli	0.5	0.5
Other cruciferous vegetables ⁵	0.5	0.5
Chicory	2	1.0
Lettuce (including cos lettuce and leaf lettuce)	10	10
Onion	0.05	
Welsh (including leek)	3.0	3.0
Celery	0.2	0.2
Tomato	2	1.0
Pimiento (sweet pepper)	3	1.0
Egg plant	0.3	0.1
Other solanaceous vegetables ⁹		2
Cucumber (including gherkin)	5	2.0
Pumpkin (including squash)	5	0.5
Oriental pickling melon (vegetable)	5	0.5

Water melon	0.5	0.5
Melons	0.5	0.5
<i>Makuwauri</i> melon	0.5	0.5
Other cucurbitaceous vegetables ¹⁰	5	0.5
Spinach	40	10
Bamboo shoots	0.2	0.2
Ginger	10	10
Other vegetables ¹²	0.2	0.2
Strawberry	0.1	0.1
Other spices ¹⁸		0.2
Other herbs ¹⁹		0.5
Cattle, muscle	0.01	
Pig, muscle	0.01	
Other terrestrial mammals ²⁰ , muscle	0.01	
Cattle, fat	0.01	
Pig, fat	0.01	
Other terrestrial mammals, fat	0.01	
Cattle, liver	0.01	
Pig, liver	0.01	
Other terrestrial mammals, liver	0.01	
Cattle, kidney	0.01	
Pig, kidney	0.01	
Other terrestrial mammals, kidney	0.01	
Cattle, edible offal ²¹	0.01	
Pig, edible offal	0.01	
Other terrestrial mammals, edible offal	0.01	
Milk	0.01	
Chicken, muscle	0.01	
Other poultry animals ²² , muscle	0.01	
Chicken, fat	0.01	
Other poultry animals, fat	0.01	
Chicken, eggs	0.01	
Other poultry, eggs	0.01	
Pepper, dried	10	

The uniform limit (0.01 ppm) is applied to commodities for which no numerical level is given in draft MRL.

The uniform limit is also applied to all other commodities not in this list.

The MRLs for propamocarb include residues of propamocarb and propamocarb hydrochloride.

Rafoxanide (antiparasitics)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle, muscle		0.03
Other terrestrial mammals ²⁰ , muscle		0.1
Cattle, fat		0.03
Other terrestrial mammals, fat		0.3
Cattle, liver		0.01
Other terrestrial mammals, liver		0.2
Cattle, kidney		0.04
Other terrestrial mammals, kidney		0.2
Cattle, edible offal ²¹		0.01
Other terrestrial mammals edible offal		0.2

The uniform limit (0.01 ppm) is applied to commodities for which no numerical level is given in draft MRL.

The uniform limit is also applied to all other commodities not in this list.

Colistin (antimicrobial)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle, muscle	0.15	0.3
Pig, muscle	0.15	0.3
Other terrestrial mammals ²⁰ , muscle	0.15	0.3
Cattle, fat	0.15	0.3
Pig, fat	0.15	0.3
Other terrestrial mammals, fat	0.15	0.2
Cattle, liver	0.15	0.3
Pig, liver	0.15	0.3
Other terrestrial mammals, liver	0.15	0.2
Cattle, kidney	0.2	0.3
Pig, kidney	0.2	0.3

Other terrestrial mammals, kidney	0.2	0.2
Cattle, edible offal ²¹	0.2	0.3
Pig, edible offal	0.2	0.3
Other terrestrial mammals edible offal	0.2	0.2
Milk	0.05	0.05
Chicken, muscle	0.15	0.2
Other poultry animals ²² , muscle	0.15	0.2
Chicken, fat	0.15	0.2
Other poultry animals, fat	0.15	0.2
Chicken, liver	0.15	0.2
Other poultry animals liver	0.15	0.2
Chicken, kidney	0.2	0.2
Other poultry animals, kidney	0.2	0.2
Chicken, edible offal	0.2	0.2
Other poultry animals, edible offal	0.2	0.2
Chicken, egg	0.3	0.3
Other poultry animals, egg		0.3
Salmoniformes		0.2
Anguilliformes		0.2
Perciformes		0.2
Other fish ²³		0.2
Shelled molluscs		0.2
Crustaceans		0.2
Other aquatic animals ²⁴		0.2

Colistin will not be permitted to remain in the commodities for which no draft MRL is established.

Note:

1. “Other cereal grains” refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.
2. “Beans (dry)” includes butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans.
3. “Other legumes/pulses” refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.

4. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.
5. "Other cruciferous vegetables" refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, *komatsuna* (Japanese mustard spinach), *kyona*, qing-geng-cai, cauliflower, broccoli, and herbs.
6. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, *shungiku*, lettuce (including cos lettuce and leaf lettuce), and herbs.
7. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, *nira*, asparagus, multiplying onion, and herbs.
8. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, *mitsuba*, spices, and herbs.
9. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.
10. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.
11. "Other mushrooms" refers to all mushrooms, except button mushroom, and *shiitake* mushroom.
12. "Other vegetables" refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.
13. "Other citrus fruits" refers to all citrus fruits, except *unshu* orange (pulp), citrus *natsudaidai* (pulp), citrus *natsudaidai* (peel), citrus *natsudaidai* (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.
14. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

15. "Other fruits" refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.
16. "Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.
17. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.
18. "Other spices" refers to all spices, except horseradish, *wasabi* (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), *yuzu* (Chinese citron) peels and sesame seeds.
19. "Other herbs" refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.
20. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
21. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.
22. "Other poultry animals" refers to all poultry, except chicken.
23. "Other fish" refers to all fish, except salmoniformes, anguilliformes, and perciformes.
24. "Other aquatic animals" refers to all aquatic animal, except fish, shelled molluscs and crustaceans.